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| viewpoints: are gm foods sufficiently regulated in the u.s.?  should there be mandatory labelling? | |
| Biotechnology critics, U.S. regulators and scientists agree that the StarLink episode (in which GM corn, approved only for animal feed, was found in taco shells) revealed flaws in the U.S. regulatory system. But they disagree on the issue of mandatory labelling of GM food products. |  |

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**Charles Margulis**

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**Unlike the rest of the world, the U.S. has very good regulatory agencies. Polls show people trust them.**

The polls actually show that this is a complete myth. In fact, the American public becomes just as wary about genetic engineering as anybody else, as soon as they know it's going on.

What the government really has done in the U.S. is collude with the biotech industry to make sure that the public is kept in the dark about this technology. FDA refused to require labeling of genetically engineered foods, against the advice of its own scientists. In 1992, the majority opinion of the scientists in the agency was that genetic engineering is different and should be regulated differently. But the FDA put out what was a political document, not a scientific document, that said genetically engineered foods are no different than natural foods, and therefore they don't need to be labeled or regulated any differently. And the other agencies pretty much fell in line with that approach. ...

**What about the U.S. Dept. of Agriculture in this issue? Have they been cheerleader, or have they been protecting our interest?**

The USDA has had over 5,000 applications for field trials of genetically engineered crops. They've never denied a single application. The agency will tell you, "Oh yes, but 13 were withdrawn." That's their idea of strict regulation. It's a joke. The USDA has virtually no regulation. Field trials go on when a company simply sends them a letter and says, "We're conducting a field trial." And then the approval is granted.   
  
**Jane Henney, M.D.**

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It's important for folks to realize that foods that are produced or generated using the tools of modern biotechnology come through three different review processes before they are ever introduced as foods. One is done by the USDA, and then there's one done by the Environmental Protection Agency [which looks] at crops that may be resistant to a particular pesticide. Before that [crop] is used or given approval, one also has to make some sort of assessment as to whether that can be used in a food that would actually reach the American marketplace. [If so,] then FDA would have to give an assessment too of the human food safety issues surrounding that product. ...

**With soybeans and corn, regulation has been voluntary so far?**

In 1992, we developed a policy for foods that were being developed using the tools of modern biotechnology. We did that to communicate to industry what we saw as the issues around these foods, and what we would expect [them to do] with respect to testing and food safety issues. ...

We clearly communicated that if foods were being changed using these methods, ... or if there was anything posed, like an allergen, we would require labeling on those particular products. [The] industry, to the best of our knowledge, ... has complied with that. ... As we have held meetings on these matters, I think we are satisfied that there were no safety issues missed. There was nothing introduced into the marketplace that would have posed a problem. ...

However, ... in order to satisfy ourselves that we are seeing everything, and to give consumers confidence that someone is watching this process very closely, we're moving now into what we call a mandatory notification process. We will assure ourselves that we will be seeing all of the things that are being developed using the tools of modern biotechnology as they might move into the marketplace.   
  
**Stephen Johnson**

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[Finding Cry9C in the Taco Bell shells indicates that] there is something wrong with the system. Something happened. Again, we don't know what the company did or did not do at this point. We don't know what a grower did or did not do. We don't know where the chain broke. What we do know is that we responded very quickly to ensure public health protection, [and it caused] us to look at these so-called split registrations. ...

The split registration would enable the corn to only be fed to cattle, rather than being allowed to go into the human food supply [for] direct human food consumption. Even though the law contemplates split registrations--and in fact directs the agency to allow those--given our experience with the taco situation, it would be an extraordinarily high hurdle for a biotechnology company to get one of these animal feed use exemptions again.

**Has this technology been rushed to market, too easily accepted by regulators?**

I certainly don't consider EPA a cheerleader either for or against the technology. Our responsibility is to make sure that our licensing decisions are based on sound science, that we make those decisions in an open, transparent way, and that in the end, we're providing complete public health and environmental protection. ...   
  
**Norman Borlaug, Ph.D.**

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I think it would be a disaster if we put regulations on now that would tie down the use of biotechnology and make it so complicated. What would happen? The private small companies--especially [the ones] that have many young people engaged in this field--would have to close their laboratories. Their business would collapse.

Then in 20 years, when we have to have [biotechnology and] we open the spigot in the research line, it's empty. ... This is why I plead that we are not too aggressive in closing down things that are new. ... If these regulations are tightened too much, it may kill biotechnology.   
  
**Jim Maryanski, Ph.D.**

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**Explain the concept of GRAS.**

Under the Food, Drug, and Cosmetic Act, food additives--things like spices and flavors and preservatives, sweeteners--are required to be approved by FDA before they can be used in food.

The definition of a food additive does have exemptions for substances that are Generally Recognized As Safe (GRAS). Congress, in enacting the requirement for food additives, recognized there were many substances that had been safely used in food, and did not want a pre-market review of all of those substances, such as sugar and vinegar and so forth. They also said that there could be scientific information, if it's generally recognized in the scientific community that the use of the substance is safe in food, that would be exempt from the pre-market approval requirement.

So we have a large class of substances--enzymes, many flavors, and many common food substances such as vinegar and sugar and salt and pepper and so forth--that are added to food but do not undergo pre-market approval because they are generally recognized as safe.

**This could apply to genetically engineered enzymes, for example?**

Yes. FDA has said that in looking at modifications by genetic engineering, there can be new substances in the food, such as a protein or an enzyme. To the extent that those substances are similar to proteins or enzymes that we have consumed safely, we would consider those to be essentially similar to substances that have been accepted as GRAS, and so we will not require pre-market approval for those substances.

We do have the legal tool to require pre-market approval if genetic modification is used to introduce a substance that's very different [and] we don't have a basis to believe that that substance is generally recognized as safe. ...

**So a potato is a potato is a potato, if it's not checked.**

Yes. There is the possibility that someone could change the potato in a way that would be significantly different. If, for example, through gene technology, a protein were introduced that was very different from proteins that we've safely consumed, FDA has authority to require pre-market approval for that protein as a food additive. ...   
  
**Jane Rissler, Ph.D.**

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**Under the Food, Drug, and Cosmetics Act, there were no regulations [of genetically modified organisms] ...**

But there could have been a choice. In 1992, the Food and Drug Administration produced a policy that it had been working on for many years. In that policy, it said, "We will treat them for the most part as substantially equivalent. Only under certain circumstances will we add any required regulatory mechanisms."

Thousands of people commented and said, "This is not strong enough. We want labeling. We want required food safety testing. We want these to be treated like chemical additives." Well, the Food and Drug Administration ignored those thousands of comments, and proceeded to treat these products really as ordinary food, except under unusual circumstances. As a result, there is only a voluntary scheme. The FDA has yet to require a single test of any foods on the market.

labeling  
  
**Jeremy Rifkin**

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We label everything in the U.S. You can look on a label on processed food and you can see the whole history of that food. Why would we make an exception when it came to GMO ingredients?   
  
**Dan Glickman**

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**[What about] labeling? [People are saying] "I don't believe it's unsafe, but I still want to know what I'm eating"?**

I generally agree with that. I think labeling is coming. I spoke last year about the fact that those companies that did not begin to go down the [road] of labeling were making a very bad marketing decision. Some people say, "You shouldn't label because the information on the label isn't useful, or you label only for health reasons." But we label for nutrition reasons now. You buy your food; it tells you how much fat, how much carbohydrate, what the calories are. I don't have any problem with labeling, as long as it's done sensibly. ... My prediction is, within 5 years or so, these things will all be labeled. ...   
  
**Joseph Hotchkiss, Ph.D.**

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**What would be the problems with mandatory labeling?**

If you're going to label anything in a food, you have to be able to enforce the truthfulness of that labeling. If you're going to say "GMO free," for example, you have to first define what that means, and develop a system for enforcing it. If I use soybean oil from a genetically modified soybean, and I cook battered fish in it and then I freeze those fish, does that fish contain a genetically modified organism or food, or doesn't it? It's not clear. Someplace, you're going to have to draw the line. What if you use an enzyme in food processing? Theoretically, tiny amounts of that enzyme could get into the food. Is that GMO or not GMO? ...

**So if you were a purist?**

You would ban an awfully lot of foods. As a matter of fact, if you went to the extreme with this issue, I would guess that there would be a majority of foods that would have to carry that kind of label.

**Would an animal that has consumed a genetically modified crop be a GMO?**

That depends on what kind of regulations they put forth. In my view, it should not be [considered genetically modified]. The genetic material from that crop does not become incorporated into the genetic material of the animal. It is simply another nutrient for that animal. But those are the kinds of issues that any labeling initiative is going to have to face and they are not easy issues. ...

**What would be your prediction if some of these things came to pass? Take the worst case scenario.**

My prediction, if the worst case labeling came in, that it would have very little effect on the technology, the implementation of that technology, or the food products that we enjoy. If you look at past history, people look at labels, they read labels, but it's not necessarily the prime reason that they buy or do not buy products.   
  
**Jim Maryanski, Ph.D.**

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**I'm trying to get an idea of the complexity of mandatory labeling. What kinds of problems would you have to wrestle with?**

First of all, you have the plant that has been developed for a particular purpose, and there may be several varieties of that plant that have been developed by recombinant DNA techniques--several varieties of BT corn, for example. But there may be other varieties of corn, and are other varieties of corn, that have been developed by different methods of plant breeding. [All of those varieties of corn] will be processed together. They will be shipped together. Then the processed products will then be introduced into many different kinds of products. So it's very difficult to distinguish which products contain material from modern biotechnology or any other particular technology. ...

**Would you like to be faced with mandatory labeling?**

For us it's more a question of the law that we have. We do, of course, have mandatory labeling for significant changes in the food. If there's a new allergen in the food that people would not expect, that must be labeled. If a consumer needs to know how to cook or prepare the food differently, that must be disclosed on the label. If the food has a different nutritional value, those kinds of changes have to be disclosed for a food developed by modern biotechnology, just as they do for other foods.

But the question about the method--which is really the question that many people would like to know--is a difficult one. Under our law, we are required to make information available if it's material to the product. We have looked very carefully at the use of recombinant DNA techniques, and we do not have any information that the simple use of the techniques creates a class of foods that is different in safety or quality from foods developed by other methods of plant breeding. So we don't have a legal basis to require manufacturers to disclose that information on the label.

Now, the manufacturers are free to disclose whether the product is developed by modern biotechnology or not, as long as they do so in a way that is truthful and doesn't mislead the consumer. ...   
  
**Jane Rissler, Ph.D.**

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**The FDA's reasoning is that if they labeled GM, they'd have to label stuff done by traditional cross-breeding.**

I don't think so at all. I think there's a very easy way to determine that these products are genetically engineered. You just label them as genetically engineered. It's like irradiated food. That is labeled. ... The FDA continues to say that there are no safety issues associated with irradiation, but they require that food be labeled as irradiated. That's because there was a great citizen outcry calling for labeling of irradiated food. The FDA has the power to require labeling if there is enough pressure to convince them to do it. It doesn't have to even be for a safety. ...

**If you produced a new product with traditional cross-breeding as opposed to with genetic engineering, why would one require more regulation? If a tomato's been produced by cross-breeding, you can call it a tomato. But if a tomato's produced by adding a gene for--**

It's still a tomato, but it has a genetic additive, and it should be treated as a tomato with a chemical additive. ...

When I was at the Environmental Protection Agency, we were trying to write rules that said that genetically engineered microbes should be looked at differently under the Toxic Substances Control Act. The Reagan Administration and a lot of other folks were opposed to that because they, too, bought into [the idea that we should] regulate the product, not the process. ... What happened over the years is that they lost that argument, because the process is regulated in the United States. We do have this regulatory apparatus that is directed at genetically engineered organisms. And it means that the USDA regulates the crops in a way it does not regulate traditional crops.

Our argument [at the EPA] was--and my argument is--that as a general matter, this is a new technology. It is a technology that brings with it a significant amount of uncertainty. It hasn't been applied. It hasn't been monitored much in the environment. ... To the extent that one has resources to try to ensure safety to the environment and to public health, you direct those resources at the things that cause the most uncertainty or present the most risk. That's why I don't look at traditionally bred crops. There may be some that are troublesome, but as a general matter, they are not. We know very little about the long-term impacts of genetically engineered food [and] they should be subject to more scrutiny. ...   
  
**Martina McGloughlin, Ph.D.**

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**[Critics] make stick the idea that although we've been modifying foods for thousands of years, we're going to treat one process differently. Is that right?**

That's a complete departure, both from the original intent of regulations on the U.S., and indeed on the European side, where the focus up until now had been on the product, not the process by which it's produced. If you look at a package of sausages, it doesn't say, "This was produced using extrusion processes." Most people would never want to see how sausages are produced. ... Agricultural practices or processing practices have never been a requirement of labeling. And now suddenly they are, which is a total departure from the way regulations have been put into place on both sides of the Atlantic.

**So now they're singling out a particular process. If it's produced using recombinant DNA ...**

Yes. If it's produced using recombinant DNA technology, then you're required to label it. There is a threshold level of 1 percent.

This decision [was] made at a parliament level; it had little input from the scientists, because every scientist will tell you [that it is] impossible to actually enforce those regulations because the type of tests that are out there are notoriously inaccurate. ...

[Researchers at] KPMG ... determined that the overall costs of ... testing will put between 5 to 15 percent of cost that will be passed on to the consumer, on all of these products. Effectively, what you're doing is imposing a tax on a technology that in fact is reducing environmental impact and potentially increasing the healthfulness and safety of our food. ...

**Nicholas Kalaitzandonakes, Ph.D.**

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**Regarding Europeans and the issue of labeling genetically modified food: They have to come up with a logical rationale for labeling food based on the process by which it's made. Is this a real tricky problem?**

It is. ... From a practical perspective, if there is any real difficulty right now in implementing labeling requirements in general, [it's because] we have a non-standardized system. In other words, if you look at what the Japanese have done with their labeling system, they require a five percent threshold, which does not cover, for example, feed, oils, or highly processed foods. The Europeans are moving towards a system that is much tighter, both in terms of the thresholds and in terms of what is being covered. The Koreans want 2 percent threshold, and so on. The infrastructure in agriculture and food is not able to handle all these different requirements. ...

**How serious is this? What problems can this cause?**

If we are going to implement labeling at a broad scale, that means that we are going to have to deal with the issue of identity preservation and traceable systems. In other words, we are going to have to be able to tell all along the supply chain in agriculture and food, where this food came from, what is in that food, and how it was produced. That's not what we do today and that would be costly. The question is: How costly? Based on our research that we published very recently, ... the cost is actually twice as large as we originally thought, because of hidden costs.

**What does that mean, practically? Consumers would pay for this?**

Absolutely. Eventually, the consumers will have to pay for this